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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/927,322

Applicant(s)

IMBACH ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 14, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. There still remains original point 5. The traverse is unpersuasive. While “heterocyclic” is defined in some places, in others it is not, so it is unclear whether applicants intend the same definition to apply everywhere, or whether the undefined uses intend something broader, and if so, what. If applicants are unable to answer the questions posed, that is some evidence that the term is unclear.
2. There still remains original point 6. Applicants argue that the term “aliphatic” “does not embrace aliphatic acyl” according to the definitions provided in the specification. The examiner does not agree, and therefore, there is clearly a lack of clarity. The specification gives an example of aliphatic acyl the acetyl group, and one of ordinary skill in the art would agree that this is an example of an aliphatic acyl. In terms of defining aliphatic radical, page 3, line 1 includes, “...substituted alkyl.....” and line 3 repeats this. No limitations are placed on the substituent.

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The acetyl group is an ethyl group substituted by oxo. One of ordinary skill in the art would further understand aliphatic as embracing acetyl, and indeed, embracing alkyl substituted by anything which does not have a ring, since the only requirement for aliphatic is that it not possess a ring. If applicants intend "aliphatic" to mean just unsubstituted alkyl, alkenyl and alkynyl, it is suggested that such claim language be used.

3. There still remains original point 10. The traverse is unpersuasive. Applicants point to "the definition and the preferred embodiments given...." But there is no definition, and preferred embodiments are just that, preferred, not required. There is nothing there to exclude something like dimethyl phosphoryl or methanesulfonyl. Further, saying RC(O) is what is intended begs the question of what is R. Can R be H? Cl? Amino? OH? Methoxy? Applicants point also to the special material for acyl appearing in R4 and R5, i.e. the acyl of 1-30 carbons. That material is clear. The problem is not this acyl but the "lower aliphatic acyl" such as appears for R6 and R7.
4. There still remains original point 12. A hydrocarbon is a group containing only C and H. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947); *Ex Parte Clifford*, 63 USPQ 19). Terms may not be "used in ways that are contrary to the accepted meanings in the art" (MPEP 2173.01).
5. There still remains original point 15. This is not a standard medical term because tumor is not an adjective. This wording could mean a disease which causes tumors,

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or a disease which is caused by tumors, or it could mean cancer or it could mean just "tumors" or it could mean something else.

6. There still remains original point 22. Compounds with braces generally are incomplete because they are missing a locant. For example, the first species on page 90 has a substituent present in braces. This could be on either ring or on the N. These names are incomplete, lacking the proper information.
7. The penultimate R4-R5 combined choice has a disagreement between the name and the chemical formula. A 2,7-diyl would have a 6 atom chain (one N, 5 C), but the material in braces is only a 5-atom chain. For whichever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended.

Claims 1-5, 14, 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A. Claim 3 contains new matter. It provides a circumstance where the definition of R4 depends on the definition of R1. No such concept existed in the claims or specification previously, let alone the specific idea that the definition of R4 depending on where or not R1 was  $\alpha$ .

B. The proviso added to claims 1-4 is new matter. The proviso lacks description. Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The reason was given previously in detail. The traverse is unpersuasive. First, the specification provides virtually no guidance at all. Pages 22-24 simply provides standard protocol for testing. Page 47 says that it refers to tumors which respond to inhibition of p34cdc2/cyclin Bcdcl3. However, this is hardly a well established set of disorders. One of ordinary skill in the art has little idea what is and is not in that category. Only extensive basic research will eventually answer that question. Second, that is irrelevant. The claims are not limited; they simply read on any tumor of any type. The PTO does not read unexpressed limitations into the claims, *In re Kebrich*, 96 USPQ 411, 413. Similar is *In re Winkhaus*, 188 USPQ 129: "We will not read into claims ... limitations from the specification."

#### *Specification*

The abstract is too long. Suggested is deletion of the  $\alpha 2$  material after "nitrogen" and the R9 definition.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch  
Primary Examiner  
Art Unit 1624

August 5, 2002